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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|----------------------|
| 10/624,534 | 07/23/2003 | Lloyd Wolfinbarger JR. | 64230-00004USD1 | 6665 |
| 7590 | 08/16/2005 | | EXAMINER | |
| JENKINS & GILCHRIST 1445 ROSS AVENUE SUITE 3200 DALLAS, TX 75202 | | | | BRADICK, THOMAS DALE |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/624,534 | WOLFINBARGER ET AL. |
| | Examiner | Art Unit |
| | Thomas D. Bradrick | 1651 |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-120 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-120 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08).
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 7-27 and 33-45, drawn to processes for preparing acellular soft tissue grafts for implantation into a mammalian system comprising extracting the tissue, treating the extracted tissue with one or more anionic detergents, washing the treated tissue with a decontaminating solution and storing the resulting tissue graft, classified in class 422, subclass 1.
- II. Claims 3-33, 42-45 and 93, drawn to process for preparing acellular soft tissue grafts for implantation into a mammalian system comprising inducing pressure mediated flows of the respective solutions to extract, treat and decontaminate the tissue, classified in class 422, subclass 1.
- III. Claims 46-54, drawn to decellularized soft tissue grafts, classified in class 435, subclass 1.1.
- IV. Claim 55, drawn to a non-immunogenic, acellular soft tissue graft, classified in class 435, subclass 1.1.
- V. Claims 56-92, 94-102, 108 and 109, drawn to a process for preparing an acellular soft tissue graft comprising optionally treating the extracted and processed tissues with hypertonic treating solutions, classified in class 422, subclass 1.

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- VI. Claims 103-107 and 110-118 drawn to an acellular tissue graft, comprising a soft tissue sample substantially free from cellular elements, classified in class 435, subclass 1.1.
- VII. Claim 119, drawn to a method for modulating recellularization of an acellular soft tissue graft upon implantation of said graft, classified in class 422, subclass 1.
- VIII. Claim 120, drawn to an acellular soft tissue graft comprising a soft tissue sample essentially free from cellular elements and precipitated anionic detergent, classified in class 435, subclass 1.1.

Claims 7-27, 33 and 42-45 are generic to Groups I and II and will be examined to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions III, IV, VI and VIII are drawn to a decellularized soft tissue graft, a non-immunogenic acellular soft tissue graft, an acellular tissue graft comprising a soft tissue sample substantially free from cellular elements and an acellular soft tissue graft comprising a soft tissue sample essentially free from cellular elements and precipitated anionic detergent, respectively. These compositions are clearly distinct and so are classified accordingly.

Inventions I, II, V and VII are drawn to processes for preparing acellular soft tissue grafts for implantation into a mammalian system comprising extracting the tissue, treating the extracted tissue with one or more anionic detergents, washing the treated tissue with a decontaminating solution and storing the resulting tissue graft; preparing

an acellular soft tissue graft comprising optionally treating the extracted and processed tissues with hypertonic treating solutions; and a method for modulating recellularization of an acellular soft tissue graft upon implantation of said graft, respectively. The processes are clearly distinct as they recite different and distinct steps that lead to different and distinct products, and so are classified accordingly.

Inventions I/II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case soft tissue such as skin can be removed using a dermatome and meshed using a scalpel prior to immediately being stapled or bolstered into place.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case soft tissue such as skin can be removed using a dermatome and meshed using a scalpel prior to immediately being stapled or bolstered into place.

Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case recellularization can be accomplished in a bioreactor using dynamic pulsatile fluid flow to expose the tissue to mechanical forces.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: nonionic detergents comprising polyoxyethylene alcohol, polyoxyethylene isoalcohol, polyoxyethylene p-t-octyl phenol, polyoxyethylene nonylphenol, polyoxyethylene esters of fatty acids and polyoxyethylene sorbitol esters; anionic detergents comprising sodium dodecylsulphate, sodium dodecylsulphonate, sodium dodecyl-N-sarcosinate and sodium suramin; antimicrobial agents comprising chlorine dioxide, ethanol, isopropanol, methanol, glycerol and methylparaben; decellularized soft tissue graft comprising a vein, an artery, a heart valve, a ligament, a tendon, fascia, dura matter, pericardium and skin; salts comprising sodium chloride, potassium chloride, lithium chloride, calcium chloride, sodium phosphate, calcium hydroxide, potassium sulfate, lithium sulfate, calcium phosphate, potassium phosphate, lithium phosphate, ammonium chloride, magnesium chloride and calcium sulfate.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Groups I, II, III and V are generic.

If Group I or II is elected, please choose a single species from claim 10, namely polyoxyethylene alcohol, polyoxyethylene isoalcohol, polyoxyethylene p-t-octyl phenol, polyoxyethylene nonylphenol, polyoxyethylene esters of fatty acids or polyoxyethylene sorbitol esters; a single species from claim 12, namely sodium dodecylsulphate, sodium dodecylsulphonate, sodium dodecyl-N-sarcosinate and sodium suramin; and a single species from claim 16, namely chlorine dioxide, ethanol, isopropanol, methanol, glycerol or methylparaben.

If Group III is elected, please choose a single species from claims 48-50, namely a vein, an artery, a heart valve, a ligament, a tendon, fascia, dura matter, pericardium and skin. Note that if applicant chooses a vein, an artery or a heart valve, claims 49 and 50 will be ignored. If applicant chooses either a ligament or a tendon, claims 48 and 50 will be ignored. If applicant chooses fascia, dura matter, pericardium or skin, claims 48 and 49 will be ignored.

If Group V is elected, please choose a single species from claim 58, namely polyoxyethylene alcohol, polyoxyethylene isoalcohol, polyoxyethylene p-t-octyl phenol, polyoxyethylene nonylphenol, polyoxyethylene esters of fatty acids or polyoxyethylene sorbitol esters; a single species from claim 61, namely sodium dodecylsulphate, sodium dodecylsulphonate, sodium dodecyl-N-sarcosinate or sodium suramin; a single species from claim 65, namely chlorine dioxide, ethanol, isopropanol, methanol, glycerol and

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methylparaben; and a single species from claim 86, namely sodium chloride, potassium chloride, lithium chloride, calcium chloride, sodium phosphate, calcium hydroxide, potassium sulfate, lithium sulfate, calcium phosphate, potassium phosphate, lithium phosphate, ammonium chloride, magnesium chloride and calcium sulfate. Also, for claim 62, please specify a particular monovalent salt, a divalent salt and an antimicrobial agent consistent with the requirements of the claim and the anionic detergent chosen for prosecution in claim 61.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims *readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is (571) 272-8139. The examiner can normally be reached Monday through Friday between 8:30 a.m. and 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas Bradrick
Patent Examiner
Art Unit 1651

Thomas Bradrick



SANDRA E. SAUCIER
PRIMARY EXAMINER